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IN THIS ISSUE

John R. Rosing, MHA, FACHE

Guest column: Rethinking performance monitoring and improvement techniques

(John R. Rosing is vice president of Patton Healthcare Consulting, which serves as technical adviser to Inside the Joint Commission.*)*

Performance Improvement monitoring, when evaluating any process that requires staff to perform in a certain manner without requiring documentation of the event in the medical record, often presents a dilemma for the PI professional because we must rely on direct observation of staff performance in order to score their compliance.

(*see* ***Rosing***, *p. 4*)

Medication management

Monitor the monitors when planning oversight of controlled substances in your pharmacy

Empower staff to be more vigilant and spread pharmacy tasks among employees to minimize the risk of inappropriate or illegal activities around controlled drugs.

In July, Anthony D'Alessandro, director of pharmacy services at Mount Sinai Beth Israel Medical Center in New York, was arrested and charged with stealing almost 200,000 oxycodone pills over a five-year span. Prosecutors say the pills were worth nearly $5.6 million on the black market. A 14-year employee

(*see* ***controlled substances***, *p. 7*)

Compliance

The Joint Commission subjects CAHs to waived testing requirements

The Joint Commission (TJC) will begin subjecting critical access hospitals to the same waived testing requirements as other hospitals as of Jan. 1, 2015.

Waived tests, such as a finger stick for blood glucose, are the lowest level of lab testing complexity under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Waived testing has fewer requirements, which are less stringent than the requirements for nonwaived testing.

"These tests employ methodologies that are so simple and accurate that the likelihood of erroneous results is negligible, or they pose no risk of harm to the patient if the test is performed incorrectly," explains Laura Smith, project director with TJC's Department of Standards and Survey Methods who deals with critical access hospitals (CAHs).

CAHs have different CoPs

CAHs had previously been exempt from TJC's waived testing standards, which include policies and procedures for waived tests, identification of staff responsible for performing and supervising waived testing, competency of staff and licensed independent practitioners performing waived tests, quality control checks, and maintenance of records for waived testing.

"CAHs have different Conditions of Participation in Medicare so one can see how [such an exemption] could have happened," says Brock Slabach, member services senior vice president of the National Rural Hospital Association in Kansas City and former administrator of a rural hospital.

The only CAHs subject to waived testing requirements were those that have a lab that is TJC accredited; they already comply with waived testing requirements as part of the Laboratory Accreditation Manual, Smith points out.

However, TJC has determined that since CAHs provide many of the same services as small and rural hospitals, they should comply with the same standards as other hospitals to ensure patient safety and quality of care.

"The Critical Access Hospital Accreditation Manual will now include the [Waived Testing] chapter just as the Hospital Accreditation Manual does. The inclusion of the waived testing requirements in the CAH accreditation manual now allows CAH surveyors to score additional issues of quality and safety they identify related to waived testing," Smith explains.

Three tips to help CAHs comply

CAHs should expect TJC surveyors to be looking at waived testing as of Jan 1, 2015. To prepare for the change, consider these three steps:

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President: Steve Greenberg
1-301-287-2734
sgreenberg@decisionhealth.com

Vice President: Carol Brault
1-301-287-2470
cbrault@decisionhealth.com

Product Manager: Yolanda Matthews
1-301-287-2412
ymatthews@decisionhealth.com

Editor: A.J. Plunkett
1-301-287-2359
aplunkett@decisionhealth.com

Technical Advisers:
Patton Healthcare Consulting, LLC
Kurt Patton, MS, R.Ph.
Jennifer Cowel, MHA, RN
John Rosing, MHA, FACHE

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• **Have the CAH's lab manager and director of clinical services get together** to review the waived testing requirements and determine what changes will need to be made to comply. "You'll now need documentation and coordination of quality controls for these processes," says Slabach. This may vary from CAH to CAH, as some of them have already been addressing these requirements, says Smith.

• **Ensure that the lab manager coordinates waived testing among hospital departments** so that there's consistency in performance and result reporting on waived tests. "You need to standardize the process and ensure that reporting is accurate," says Slabach. "Facilities may be doing it informally. Now you need more documentation," he adds.

• **Make sure that your CAH is up to date on waived testing.** For instance, TJC issued a new answer to a frequently asked question (FAQ) on the competence of independent practitioners to perform waived tests in April; that, as well as other FAQs, will apply to CAHs as of Jan. 1, 2015.

And on July 18, CMS released the latest list of new waived tests approved by the Food and Drug Administration under CLIA, effective Oct. 1, 2014, with an implementation date of Oct. 6, 2014. There are 25 new waived tests on the list, including certain thyroid screens and hemoglobin testing systems. — *Marla Durben Hirsch (mdurbenhirsch@decisionhealth.com)*

Resources:

- New Joint Commission FAQ on waived testing: *http://tinyurl.com/TJC-FAQ-waived*
- CMS information on new waived tests: *http://tinyurl.com/CMS-waived*

Emergency planning

Use Ebola warning to review hospital infection disease controls and policies

The CDC recommends hospitals review precautions for dealing with suspected Ebola patients.

While saying the Ebola virus poses no significant threat to the United States, the CDC issued its recommendations on Aug. 1, about the same time news organizations began reporting that the first of two infected American health care workers were being brought back to the U.S. for treatment.

The widening outbreak of the deadly hemorrhagic fever in West Africa has caused particular concern because of the number of health care workers who have been infected despite apparently taking standard precautions.

The CDC recommendations on "standard, contact and droplet precautions" include instructions on keeping patients in isolation, providing health care workers with proper personal protective equipment (PPE) such as fluid impermeable gowns and face shields, dedicating medical equipment for use with only that patient, proper hand hygiene, safe patient handling procedures and diligent environmental cleaning, among others.

The recommendations also refer hospitals and other providers to the CDC's 2007 "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings."

For now, hospitals should have their infectious disease team and administration review the CDC recommendations and "gap analyze" them against current policy and procedures in case the precautions include any new instructions or unique nuances, says John R. Rosing, vice president of the Glendale, Ariz.-based Patton Healthcare Consulting, which serves as technical adviser to *Inside the Joint Commission*.

"New policy and procedure may be warranted to cover these nuances (e.g., new details in the "Monitoring and Management of Potentially Exposed Personnel" section)," notes Rosing. The team should also review their understanding of the CDC's 2007 guideline for isolation precautions, he recommends.

"Determine which, if any, points in these guidelines the team feels need to be reinforced or revisited for caregivers within the organization. The team should also inform providers at all points of entry (ED, urgent care centers, primary care clinics, etc.) of the symptoms of Ebola Hemorrhagic Fever infection and modes of transmission," Rosing says.

"A second thing hospitals should consider is reviewing the infection control risk assessment they have in place to see if they want to reposition, or re-score the risk of transmission of infection from an influx of infectious disease patients," adds Jennifer Cowel, a nurse and a Patton Healthcare Consulting vice president.

"Hospitals are to do a risk assessment annually or whenever there is a significant change," Cowel notes. Be sure to include the hospital's policy for handling an influx of infectious disease patients in any gap analysis.

"Finally, as the hospital makes plans for emergency drills for the upcoming year, they should consider whether it is time to do a drill based on influx of infectious disease patients. The drill could assess the hospital's readiness to accept a patient with a specific infectious disease," she advises.

"Events like these are a wake-up call, and time to reassess readiness. Influx of infectious disease was a big issue when H1N1 was an issue three years ago, but it has not been on radar as of late." — *A.J. Plunkett (aplunkett@decisionhealth.com)*

Resources

- CDC recommendations for hospitals: *http://www.cdc.gov/vhf/ebola/hcp/infection-prevention-and-control-recommendations.html*
- General CDC Ebola information: *http://www.cdc.gov/vhf/ebola/*
- 2007 Isolation precautions guidelines: *http://www.cdc.gov/hicpac/2007IP/2007ip_part2.html#e*

CMS

IPPS final rule for 2014 increases VBP, readmissions penalties

The quality of care and readmission rates for inpatients discharged on or after Oct. 1, 2014, could have an even more dramatic impact on a hospital's bottom line as CMS raises the penalties under the federally mandated value-based purchasing (VBP) and readmissions reduction programs.

In a final rule on the Inpatient Prospective Payment System (IPPS) issued on Aug. 1, CMS set new parameters for the programs. The reduction of Medicare payments will go up to 1.5% to fund the VBP program that pays incentives to hospitals that show improvement in quality of care. At the same time, the maximum reduction in Medicare payments under the readmissions program will go from 2% to 3%.

And beginning in fiscal 2015, which begins Oct. 1, hospitals who have the worst performance in reducing hospital-acquired conditions will have payments reduced by 1%.

In addition, under the IPPS final rule, Oct. 1 marks the beginning of a two-year transition for some critical access hospitals (CAHs) that CMS believes no longer qualify for CAH status. Hospitals that want to retain the status must reclassify as rural.

To read the final rule, go to *http://tinyurl.com/CMS-IPPS-2014-Aug*. — *A.J. Plunkett (aplunkett@decisionhealth.com)*

Rosing

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By its very nature, direct observation as a PI monitoring technique is highly susceptible to the "Hawthorne Effect," where staff may fool you into thinking all is well when in fact they only raise their level of performance for the particular task because they know you are watching them.

Many of The Joint Commission's National Patient Safety Goals and standards carry this vulnerability. For instance, direct observation is the customary method of monitoring the use of two identifiers prior to medication administration or meal tray pass, read-back of telephone orders or critical results, hand-off at shift report, hand hygiene, or even the rigor with which the time-out occurs prior to surgical incision.

Another complicating factor is the failure to "spread" a particular performance-related policy or process hospital-wide.

Often, with good intentions, we inadvertently design a policy or process to fit a major-user department without making adequate concessions for how the process might need to work differently in a smaller department. So staff members in the smaller department develop work-arounds or short-cuts to account for the misfit elements of the policy that they deploy each day, but may be tempted to mask from you when they know you are there watching to monitor their performance.

When faced with this monitoring dilemma it may prove fruitful to augment the direct observation PI method with a focus-group technique. In this approach, you periodically gather a group of like-staff together in a non-punitive/no harm session and begin by briefly

reviewing the policy in question, and then ask them open-ended questions such as:

- When might you not follow the policy?
- What variables (time of day, day of week, the type of patient, the type of medication, etc.) cause minor or major variation in how the process works in real life?
- What gets in the way of flawless performance of this policy?
- What work-arounds have crept into the process?
- What is your chief complaint about this policy?
- Is your having too little time ever a reason to think about employing a work-around?
- Is this "right thing to do" indeed the "easiest thing to do" or is a short-cut the easier thing to do?

As you consider and aggregate the responses you receive from staff, think of ways to introduce forcing functions to make the process more fool-proof, less variable, and more consistently safe.

Employing the focus-group method as an additional tool in your PI quiver will likely improve reliability and flawless implementation of performance-related processes in your unit and organization.

(For Rosing's five steps to spreading performance improvement-driven change through your organization, see below.)

John Rosing, MHA, FACHE

Achieving success: The five steps (plus one) to doing the 'right' thing 'well'

The Five Step (Plus One) process emphasizes the important role of the day-to-day line manager in owning and spreading each performance improvement-driven change in a process or ongoing sustainability of an existing process.

Resources, such as interdisciplinary design teams, educators, organization development and performance improvement (PI) staff provide guidance and assistance, but for changes to be effective and lasting, senior operations leadership and line managers must together own responsibility for sustained execution and spread.

- **Step 1: Process Design or Redesign**

The first step in this five-step process is the design of processes. In some cases, it may be a new process and in other cases it may be a redesign of an old process. Strive to make the right thing to do the easiest thing to do, and keep things as simple as possible. Interdisciplinary improvement teams using tools such as PDSA, Lean, and Six Sigma will help prioritize and accelerate efforts toward successful new or redesigned process implementation.

- **Step 2: Educate and Train**

Once a process has been well designed and pilot tested, an education plan should be developed. Staff will need to be taught and trained on the new process. The key is to incorporate someone with the experience and expertise in education and training to consult with you on what would be the best way to teach this new process (e.g., the book by Donna Wright, "The Ultimate Guide to Competency Assessment in Health Care.") Hospital educators can be a valuable resource to help design the education plan. But the education itself and the steps 3-5 that follow should be driven locally by unit directors, managers and supervisors down to each individual staff member.

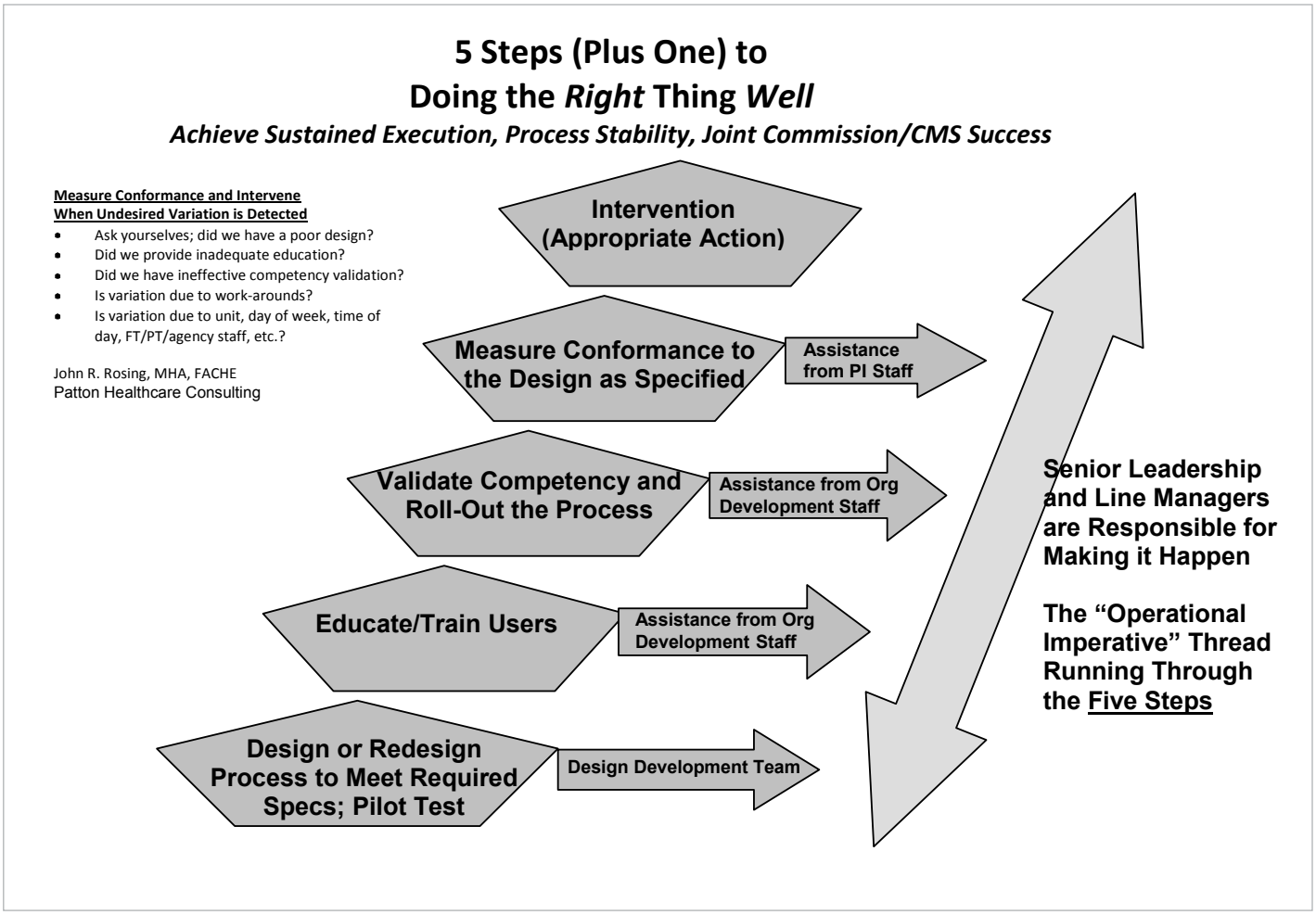
- **Step 3: Validate Competency**

Once the manager has educated staff, the next step is to confirm comprehension and proficiency by validating competency. This is a separate step from training and may occur in a "test" environment prior to rollout or in real-time along with rollout.

Attendance at an in-service is usually not enough to demonstrate competence validation. There must be a way to confirm and satisfy you, the manager, that those you just taught can now go out and apply this new knowledge.

There are different ways to do this. Paper and pencil tests, return demonstration, skills lab, and verbal recitation of the policy are all possible methods. There is a skill in choosing the best method. An educator or another resource may help choose the method to best validate competency for a given subject matter. Once competency has been validated, it should also be documented in an employee's competency folder, either on paper or electronically in a system like "Learning Central."

Make sure you affirm those who are doing it right while coaching and counseling those who are doing it wrong. Give opportunities to improve and make interventions when needed, always revalidating the competency until the staff member can demonstrate compliance with the new process or policy.



- **Step 4: Measure Conformance**

After you have completed the validation and implementation, the next step is to evaluate, or "measure conformance." Measurement of conformance should be precise and measure against the specifications required by the design. You should not allow staff to work around what was designed or make up their own version. Only by measuring to precise specifications will process variation be sufficiently narrowed to ensure ongoing process stability and sustainability.

How are you going to measure that conformance? A conformance measurement plan should be designed with the assistance of performance improvement staff or other resources in the organization that possess expertise in data collection, proper sample sizes, display of data, etc. The data itself should be collected at the unit level, individual by individual.

The goal is to measure conformance in order to ensure that staff is habitually and reliably following the design. Conventional wisdom has been to sample 30 charts or some other number to measure conformance in a random and statistically significant manner. What is proving to be more effective is to instead look at one or two cases from each person in your respective area, study their performance individually and give them personal feedback. This allows a very discreet and impressionable means to either affirm desired behavior or change undesired behavior outside of the performance appraisal process and outside of all the tension that comes from boss/employee or superior/subordinate relationship. This merely becomes a coaching exercise. This has been shown to have a huge impact on staff and instills pride and ownership. It's deliberate, it's discreet, it's one on one, and it's powerful in narrowing variation around what was designed.

- **Step 5: Intervention**

The fifth step, an intervention plan, happens when the data show there is wide spread failure to perform a new policy or process correctly after implementation.

The question at this time should be "where do we need to step back and look again?" It could be that a big part of the process was missed during the design step, re-education of the process needs to occur, a different teaching method needs to be used to validate competency, or perhaps the measurement technique was flawed.

The answers can be found by going back to one of the previous four steps. Line management's goal is to uncover why the process is it failing and backfill to repair it. Sometimes it's as simple as affirming what people are doing, saying thank you and reinforcing that. Other times it's just a matter of holding people accountable. Or it might require a return to the design table/drawing board.

- **(The "Plus One" Step) Narrowing Variation in Implementing Steps 2-5**

Many of the processes or policies that are designed by a team will be spread to seven, eight, 10, or even 12 different departments. As much as possible, narrow variation around how individuals charged with implementing the process understand and implement the process. Twelve different managers teaching, validating competency or measuring conformance 12 different ways will result in too much variation. The key is to define up front the best way to accomplish each of steps 2-5 prior to roll-out of the process. — *John R. Rosing, MHA, FACHE (johnrosing@pattonhc.com). Rosing is vice president and principal of Patton Healthcare Consulting, which serves as technical adviser to* Inside the Joint Commission.

controlled substances

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who was dismissed in the spring, D'Alessandro was responsible for all medication stocks and is charged with removing pills on 220 separate occasions.

The case illustrates the dangers of concentrating high levels of authority in one official, and the need for adequate oversight practices and even monitoring by other employees, say pharmacy administration experts. D'Alessandro has pleaded not guilty.

Hospitals must report 'abuses and losses'

Under the Medication Management chapter, The Joint Commission (TJC) requires hospitals to plan its management processes, and **MM.01.01.03** especially points to "high-alert and hazardous medications," which include controlled substances. In particular, **Element of Performance (EP) 5** states that hospitals that use commission accreditation to qualify for Medicare reimbursement must report "abuses and losses of controlled substances," according to law and regulations, "to the individual responsible for the pharmacy department or service and, as appropriate, to the chief executive."

In addition, under **MM.03.01.01**, which requires hospitals to safely store medications, **EP3** requires medications to be stored "in a secured area to prevent diversion," while **EP4** requires a written policy that includes "the control of medication between receipt by

an individual health care provider and administration of the medication," and **EP6** requires the hospital to prevent "unauthorized individuals from obtaining medications in accordance with its policy and law and regulation."

The New York case should spur hospitals to review their own oversight plans, says Kurt Patton, president of Patton Healthcare Consulting in Glendale, Ariz., technical adviser to *Inside the Joint Commission*.

"This is a big teaching hospital and the pharmacy director is a senior administrator in the hospital," observes Patton, who is also a pharmacist by training. "Staff should have asked 'what's the director doing in the vault room?' Every episode like this requires introspection. Would our organization have been able to detect this ahead of time?" notes Patton.

Ensure separation of power

Make a conscious effort to distribute responsibilities among staff members, so that one employee cannot unilaterally acquire controlled drugs without drawing notice.

"There must be a system of internal controls just like you would have for general purchasing and procurement of goods," said Douglas J. Scheckelhoff, vice president in the Office of Practice Advancement at the American Society of Health-System Pharmacists, a nonprofit society based in Bethesda, Md.

"When one person routinely performs more than one of these activities without any oversight, it removes necessary checks and balances … No one person should have complete control over the entire system without independent checks and periodic audits."

Scheckelhoff recommends distributing the following tasks among different pharmacy department employees:

- Approval of purchases and orders.
- Receipt of shipments.
- Approval of payments.
- Auditing of transaction records.
- Drug transfers.
- Performing inventory counts.

Monitor drugs across departments

Establish a drug ordering system that works across departments, tracking not only when drugs are issued but when they are received, and ensuring that quantities and other parameters match.

"When you issue a controlled drug to a department, there should be a corresponding appearance of that issuance in the user department," Patton suggests. "If it doesn't show up, there should be a system to notice this."

Electronic health records, digital order entry systems and other health IT mechanisms can be a user-friendly and relatively painless way of tracking drugs in the pharmacy department and throughout the organization.

"Fortunately there are automated systems that provide for both secure storage and record keeping, and represent a big improvement over the manual systems used in the past," Scheckelhoff says. "These automated systems also generate a number of variance reports designed to point out discrepancies, such as unusually high usage by one area or one individual, and prompt further investigation."

Follow these tips to ensure security

Other advise from Scheckelhoff includes:

- **Make the pharmacy director responsible** for creating a reliable and transparent system for managing controlled substances, with built-in checks and balances. Then ensure other pharmacy staff and relevant hospital leaders understand and can access the system, so that it is not centralized with one person or office.
- **Be sure you are following all applicable state and federal regulations** regarding procurement, dispensing procedures, and record keeping.
- **Consistently update inventory records,** whether on paper or in a computer-based system.
- **Regularly audit the dispensing and receipt** (using two independent, accountable individuals) of controlled pharmaceuticals. Also add an internal control to check that records are not being falsified. At least some audits should be unannounced.
- **Create an environment in which staff feel safe reporting suspicious activity.** That includes having a mechanism for safely reporting suspicions.

— Scott Harris (scottharriswriter@gmail.com)